

Applicant : N. Garison Ruggles  
Serial No. : 10/053,501  
Filed : November 2, 2001  
Page : 3

Attorney's Docket No.: 11377-019001

Applicant hereby affirms the election of Group I.

On page 5 of the office action, the Examiner has required that applicant make an election of species in seven categories. Applicant respectfully traverses the requirement with respect to election requirement (a). The Examiner has required that applicant elect one of the species within the Markush group of original claim 3. However, a combination of compounds in the Markush group is necessarily present in all extracts of *G. glabra*. It is respectfully submitted that if the Examiner wishes to reduce the burden of search by requiring an election of species, a more reasonable election would be among the members of the Markush group in claim 1, part (a). This is submitted to be reasonable since in applicant's examples, the active ingredient is identified as an extract, and not as a specific compound contained within the extract. Within the Markush group in claim 1 (a), applicant can only elect the species of an extract of *G. glabra* or an anti-odor and anti-plaque component of the extract, since the other two members of the Markush group are already subject of non-elected inventions pursuant to the restriction requirement. Accordingly, the applicant elects the species of an extract of *G. glabra* to respond to the election of species requirement.

With respect to election of species requirement (b), applicant elects the species of cationic surfactant.

With respect to election of species requirement (c), applicant elects a divalent zinc cation.

With respect to election of species requirement (d), applicant elects the aqueous composition of claim 1. Accordingly, claims 13-35 have been cancelled as being directed to non-elected species.

The requirement for election of species (e) and (f) are moot in view of the election of the aqueous compositions.

With respect to election of species requirement (g) applicant elects inulin.

All of the remaining claims read on the elected species.

Claims 1-4, 6, 7, 10, 11 and 36 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baxendale (A) taken with Sun Star (N), Suido (O), and Nishida (P). This rejection is respectfully traversed. Baxendale does not disclose an aqueous composition for oral use comprising a water-insoluble anti-odor and anti-plaque extract of *G. glabra* and a cationic surfactant. Baxendale is directed to topical creams for treatment of inflammatory and viral

Q

infections. Baxendale is not directed to compositions for oral use, which they distinguish from their invention in column 1, lines 11-25. By implication, the prior oral compositions discussed by Baxendale are not aqueous since they are described as being adherent to moist mucous membranes, but designed not to be used in water containing compositions.

Baxendale discloses glycyrrhetic acid derivative-containing topical creams which are advantageous because they are stabilized in the water-soluble creams by the presence of zinc sulfate, zinc chloride, zinc citrate, zinc acetate, magnesium sulfate or calcium chloride. Indeed, Baxendale conducts an experiment to show which additives are effective and ineffective in stabilizing the glycyrrhetic acid derivative in the cream. See column 2, line 54 through column 4, line 47. As discussed in column 3, lines 42-45 and in table 1 (column 4, lines 1-14), the only additive which satisfactorily stabilizes the cream is zinc sulfate. One of the tested additives, cetyl pyridinium chloride (sample 7), converting the cream to a 20% content of the undesired oxolone compared to the presence of only a detectable amount of the desired carbonoxlone. Thus, according to the teachings of Baxendale, if one is to make a water-soluble cream containing a glycyrrhetic acid derivative one should add zinc sulfate as a stabilizing agent and not cetyl pyridinium chloride. This is an exact teaching away from the present invention since a cationic surfactant, is a recited component of applicant's compositions.

This deficiency is not remedied by reference (N). Although reference (N) discloses oral compositions that contain an oil soluble extract, the compositions do not contain a cationic surfactant.

Reference (O) has a similar disclosure of oral compositions containing an oil soluble glycyrrhizic extract, which does not contain a cationic surfactant.

Reference (P) is even less relevant in that it merely discloses the extraction of glabridin or glabrine from licorice root and the testing of alcohol solutions of those compounds in rats. No specific compositions or required components of those compositions for oral treatment are disclosed. Accordingly, it is respectfully submitted that the claims are unobvious over the combination of references and reconsideration and withdrawal of those rejections are respectfully requested.

a

Claims 1-4, 6, 7, 10, 11 and 36 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by each of Baxendale (A), Ebine (B), Ishigoro (C), Yamogisti (D) and Oshino (E). This rejection is respectfully traversed and reconsideration is requested.

Baxendale has been discussed above. The compositions of Baxendale are not oral compositions. The disclosed formulations and examples 1-5 do not contain a cationic surfactant. The only composition which does contain a cationic surfactant, sample 7 in the comparative testing columns 3 and 4, does not contain a water-insoluble extract of G. glabra. Accordingly, withdrawal of this rejection is requested with respect to Baxendale.

Ebine (reference B) does not disclose a composition for oral use comprising a water-insoluble fraction of G. glabra. In example 1 there is a composition of a liquid dentifrice showing as one component the dipotassium salt of glycyrrhizinate, but it does not contain a cationic surfactant. Another liquid dentifrice is disclosed in example 4 containing cetyl pyridinium chloride, but it does not contain an extract of G. glabra. In example 8 there is disclosed a composition containing glycyrrhetic acid but it does not contain a cationic surfactant. Nowhere in the references is disclosed a subcombination of the water insoluble extract of G. glabra with a cationic surfactant functioning as an anti-odor and anti-plaque composition for oral use.

Ishiguro (reference C) discloses liquid oral compositions comprising water soluble copper compounds. None of the examples disclose a composition containing a water-insoluble extract of G. glabra. The effective ingredient in the composition is the water soluble copper compound. Although optional, additional active compounds are discussed in column 3, lines 1-13, including glycyrrhizic acid, it is not disclosed as being used as a water-insoluble extract from G. glabra. Furthermore, while surfactant agents are mentioned in column 2, lines 60-65, they are not cationic surfactant agents.

Yamagishi (reference D) and Oshino (reference E) have similar disclosures. The active ingredient in compositions of Yamagishi is a monophosphate compound while in Oshino it is a quaternary ammonium phosphate salt. In Yamagishi the surfactants are discussed in column 4, lines 19-37, but cationic surfactants are not disclosed. Glycyrrhetic acid and dipotassium glycyrrhizinate are disclosed as optional additional active compounds (column 4, lines 55-61), however, these are not disclosed as being used as a water-insoluble extract of G. glabra. Oshino